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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,989	03/20/2000	Jean Marie Vogel	9676-292	6000

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EXAMINER	
WANG, SHENGJUN	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/528,989	VOGEL ET AL	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,8,11-20 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8,11-20 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on March 4, 2005 has been entered.

Double Patenting Rejections

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-4,7,8,11,14-20, and 52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,335,028. Although the conflicting claims are not identical, they are not patentably distinct from each other because '028 claims a method of using a composition comprising biocompatible cationic hydrophilic flexible microparticles, wherein the composition is injectable. The hydrophilic flexible particles are interpretated as substantial spherical, and swellable. See the

drawings therein. It would have been obvious to one of ordinary skill in the art to make a composition as herein claimed and use it in the method of '028. Note, the employment of particular carrier or other therapeutical agents herein would have been obvious to one of ordinary skill in the art, as they are well known pharmaceutical carrier and agents and would have reasonably expected to be useful in the method of '028.

4. Claims 1-4,7,8,11,14-20, and 52 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 6,660,301. Although the conflicting claims are not identical, they are not patentably distinct from each other because '301 claims a method of using the composition herein and a kit comprising the composition herein. It would have been obvious to one of ordinary skill in the art to make the composition herein for use in the method and kit in '301.

5. Claims 1-4,7,8,11,14-20, and 52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 6,790,456. Although the conflicting claims are not identical, they are not patentably distinct from each other because '456 claims an essentially same composition but with a broader scope with respect to the injectability. Particularly, '456 require the composition be injectable through needles of about 30 gauge or smaller. If a composition is injectable through needles of about 30 gauge or smaller, it will certainly be injectable through needles larger than 30 gauge.

Claim Rejections 35 U.S.C. 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-4,7,8,11,14-20, and 52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for disclosed in examples 1-20 herein, does not reasonably provide enablement for the "biocompatible, swellable, hydrophilic, non-toxic and substantially spherical microspheres" which is suitable for injection though a needle of about 18-26 gauge and are suitable for tissue bulking and would swell to a predetermined size after injection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The claims herein merely defined by various functions and without any limitation as to the materials employed therein. The claims broadly cover any composition that meet those functional limitations. In order to meet such limitation, a skilled artisan need to find a suitable materials with a suitable method to make such composition. The application provides only one particular type of polymer, i.e., polyacrylate, with a specific method of making such polymer so that spherical polymeric particle are produced in proper size. See the examples. There is no further guidance, direction, or working examples as to the method of making such polymeric particles with other polymers. The state of the prior art indicates that there is no established method for making a composition that meet all the limitation set forth in the claims. A skilled artisan would require to perform a large amounts of experimentation to find a suitable way for making substantial spherical particles from those polymers which are biocompatible, swellable, hydrophilic and non-toxic, wherein the particles are suitable for injections through a needle of about 18-26 gauge. Applicants fail to provide information allowing skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of substantial spherical particle examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of polymers required, and method of making the particles from the polymer. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. The instant claims read on all compositions meet the functional limitations herein, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention, absent undue experimentation. Attention is further directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at

the point of novelty as herein employed: the vice of a functional claim exists not only when a claims is wholly functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty. Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate. Claims employing functional language at the point of novelty, such as Applicants, neither provide those elements required to practice the inventions, nor inform the public during the life of the patent of the limits of the monopoly asserted *General Electric Company v. Wabash Appliance Corporation et* supra, at 468.

Claim Rejections 35 U.S.C. 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Boschetti et al. (US 5,635,215 IDS).

4. Boschetti et al. teaches the spherical particles herein and suspension composition comprising the same used for injection. The particles are made of polyacrylic polymer with about 10% of bifunctional monmore. The particle sizes are range from 10 um to 2000 um. specific range of particle size within the range of 10 μm to 2000 μm are disclosed. See,

particularly, the examples 1-21. Note the intended use herein, i.e., "for tissue bulking" is not seen to further limit the composition. As to the limitation of "injectable through needles of about 18 to 26 gauge." Note the particle disclosed by Boschetti et al. such as those with 300-400 μm would have reasonably expected to be injectable through such needles.

Claim Rejections 35 U.S.C. 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-4, 7, 8, 11-20 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boschetti et al.

7. Boschetti et al. teaches the spherical particles herein and suspension composition comprising the same used for injection into tissue. The particles are made of polyacrylic polymer with about 10% of bifunctional monmore. The particle sizes are range from 10 um to 2000 um. specific range of particle size within the range of 10 μm to 2000 μm are disclosed. See, particularly, the examples 1-21. The particles may be incorporated with other agents, such as dye, magnetic resonance imaging agent, or contrasting agent. The particle s may also carry cell adhession promoter. See, columns 3, lines 16-36, and the claims.

8. Boschetti et al. do not expressly disclose the composition would be injectable through needles of about 26 to 18 gauge, or the particular amount of the particles in the composition, or the other particular agents in the composition as recited herein.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to adjust the particle size within the disclosed range so that the composition would be suitable for injection with any needle required in the method.

A person of ordinary skill in the art would have been motivated to adjust the particle size within the disclosed range so that the composition would be suitable for injection with any needle required in the method because it is disclosed that the composition should be injectable. Further, employment of suitable carrier for an injectable composition, such as saline solution, would have been obvious to one of ordinary skill in the art because saline is a well known biocompatible carrier. Further, the incorporation of other well-known therapeutical agents, such as anti-inflammatory agents, or cells, with the particle would have been obvious since the other agents are known to be useful as therapeutical agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

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Art Unit 1617